

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

FILED
NICHOLAS J. MARBLEY
CLERK OF COURT

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U.S. DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA

Plaintiff,

vs.

NICOLE GEORGES,

Defendant.

Case No. 2:20-cr-157

Chief Judge Algenon L. Marbley

18 U.S.C. § 371

42 U.S.C. § 1320a-7b(b)(1)(B)

18 U.S.C. § 2

FORFEITURE ALLEGATIONS

SUPERSEDING INDICTMENT

The GRAND JURY charges:

At times material to this Superseding Indictment:

GENERAL ALLEGATIONS

The Defendant, Related Individuals, and Entities

1. Defendant NICOLE GEORGES ("GEORGES") was employed as a sales representative and supervisor of the pharmaceutical company Insys Therapeutics ("Insys"). Insys was incorporated in Delaware and headquartered in Chandler, Arizona. GEORGES was employed by Insys from approximately June 2014 until approximately February 2018.

2. From approximately June 2014 to December 2015, GEORGES was employed by Insys as a Specialty Sales Professional. In that capacity GEORGES was compensated by Insys, in part, with sales commissions based upon the dispensing of Subsys, an Insys medication that will be described in more detail below, resulting from prescriptions written by practitioners in GEORGES' sales territory. GEORGES' sales territory included areas within the Southern District of Ohio. GEORGES was later promoted to District Sales Trainer in approximately

December 2015 and District Sales Manager in approximately September 2016. GEORGES was responsible for the same sales region in both positions.

3. Jimmy Henry (“Henry”) was a licensed medical doctor in Ohio. Henry was registered with federal and state authorities in Ohio to prescribe Schedule II – V controlled substances. Henry was also enrolled with the Medicare program as a Medicare provider, and with the Ohio Medicaid program as a Medicaid provider, since at least 2010.

4. Midwest Spine and Pain (“Midwest”) was a purported medical practice which operated out of multiple locations, all in the Southern District of Ohio. Henry owned and operated Midwest and prescribed controlled substances, including highly addictive opioids, through these facilities. As the owner and operator of Midwest, Henry also entered into agreements with Medicare and the Ohio Medicaid Program, among other insurance plans, to provide reimbursement for certain services provided at Midwest.

5. In her capacity as a Specialty Sales Professional for Insys, GEORGES’ sales territory included Henry and his Midwest medical practices. GEORGES worked with Henry, including onsite at Midwest locations, regularly from at least October 2014 to at least December 2015.

Background on Subsys Fentanyl Spray

6. Opioids were a therapeutic class of drugs used to relieve pain. Fentanyl was among the most potent opioids available for human use. Fentanyl was classified as a Schedule II controlled substance. Fentanyl pharmaceutical products were available in multiple forms, including extended-release transdermal patches and injectable formulations. Transdermal patches were used in the management of chronic pain in patients who require continuous opioid

analgesia. Fentanyl was a potent opioid medication and could be abused for its intense euphoric effects.

7. On or about March 4, 2011, Insys submitted an application to the United States Food and Drug Administration (“FDA”) seeking approval of a new sublingual fentanyl spray, which it named Subsys, for introduction into interstate commerce. In approximately January 2012, the FDA approved Insys’ application to market Subsys for one purpose¹: “For the management of breakthrough pain in adult cancer patients who were already receiving and who were tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.” Breakthrough cancer pain was severe pain that erupted in patients with cancer who were already medicated with a long-acting painkiller. Due to its potency and the potential for addiction, the FDA-approved label for Subsys warned that the drug posed risks of misuse, abuse, addiction, overdose, and serious complications due to medication errors. Explicit warnings on the Subsys label included that, as an opioid agonist, the drug could be abused in a manner similar to other opioid agonists.

8. The FDA classified Subsys as fitting into a category of fentanyl-based rapid onset opioid drugs known as Transmucosal Immediate Release Fentanyl (“TIRF”) products. Because of the risk of misuse, abuse, addiction, and overdose associated with TIRF drugs, including Subsys, the FDA designed and mandated a TIRF Risk Evaluation and Management Strategy (“TIRF REMS”). As part of the TIRF REMS program, the prescriber and the patient must fill out and sign a Patient-Prescriber Agreement Form prior to Subsys being prescribed.

¹ An FDA-approved purpose for a controlled substance is also called an “indication.”

9. Subsys was prescribed in dosage strengths of 100, 200, 400, 600, 800, 1,200, and 1,600 micrograms. Subsys, like other TIRF drugs, was expensive. The approximate retail cost of Subsys ranged from just under \$2,000 per month for 30 doses of Subsys at 200mcg to over \$8,000 per month for 30 doses of Subsys at the highest dosage of 1,600 mcg. The cost of Subsys sometimes exceeded \$16,000 per month if multiple doses per day were prescribed.

10. The cost of Subsys was often subsidized by federal health care benefit programs such as Medicare and Ohio Medicaid, among others. Most insurers required prior authorizations before reimbursing for TIRF medications like Subsys. Insurers would cover the cost of Subsys prescriptions under certain circumstances, such as an appropriate cancer diagnosis and explanation of the patient's breakthrough cancer pain which went untreated by other means.

The Medicare Program

11. The Medicare program ("Medicare") was a federal health care program, affecting commerce, that provided benefits to persons who were 65 years of age or older or disabled. Medicare was administered by the United States Department of Health and Human Services, through its agency, the Centers for Medicare and Medicaid Services ("CMS"). Individuals who received benefits under Medicare were referred to as Medicare "beneficiaries."

12. Medicare covered different types of benefits and was separated into different program "parts." Medicare Part D subsidized the cost of prescription drugs for Medicare beneficiaries.

13. Generally, Medicare Part D covered part or all of the costs of prescription drugs dispensed to a Medicare beneficiary if, among other requirements, the prescription drugs were medically necessary and ordered by a physician. However, Medicare Part D only covered drugs

that were dispensed upon a valid prescription and for a “medically accepted indication.” 42 U.S.C. § 1395w-102(e). Under the Medicare Prescription Drug Benefit Manual, to be covered by Medicare, “a Part D drug must be used for a medically-accepted indication that facilitates the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Chapter 6, Section 10.6.

14. In order to receive Medicare Part D benefits, a beneficiary enrolled in one of several Medicare drug plans. Medicare drug plans were operated by private health care insurance companies approved by Medicare. Those companies were often referred to as drug plan “sponsors,” each of which dictated the specific prescription drugs covered and how much would be paid for those drugs. Medicare, through CMS, compensated the Medicare drug plan sponsors for providing prescription drug benefits to beneficiaries.

15. Medicare and Medicare drug plan sponsors were “health care benefit program[s],” as defined by Title 18, United States Code, Section 24(b), and “federal health care program[s],” as defined by Title 42, United States Code, Section 1320a-7b(f).

16. As part of the Medicare enrollment process, health care providers, including physicians, submitted enrollment applications to Medicare. To participate in Medicare, including Medicare Part D, providers were required to certify that they would comply with all Medicare-related laws, rules, and regulations, including, among others, the federal Anti-Kickback Statute. Medicare providers were given access to Medicare manuals and service bulletins describing procedures, rules, and regulations.

The Ohio Medicaid Program

17. Medicaid, established by Congress in 1965, was a federal- and state-funded health care program providing benefits to individuals and families who met specified financial and other eligibility requirements, and certain other individuals who lacked adequate resources to pay for medical care. CMS was responsible for overseeing the Medicaid program in participating states, including Ohio. Individuals who received benefits under Medicaid were referred to as Medicaid “beneficiaries.”

18. Ohio Medicaid was a “health care benefit program” as defined by Title 18, United States Code, Section 24(b), and a “federal health care program[s],” as defined by Title 42, United States Code, Section 1320a-7b(f).

19. The Ohio Department of Medicaid (“ODM”) administered the Medicaid program in the State of Ohio. ODM received, reviewed, and paid Medicaid claims submitted by health care providers, including claims for professional services, such as office visits and medical procedures, as well as for prescription drug benefits.

20. Pursuant to the rules and regulations issued by ODM, Medicaid covered the costs of certain medical services, products, and benefits, including prescription drug benefits, for Medicaid beneficiaries. Generally, Medicaid covered part or all of the costs of prescription drugs dispensed to a Medicaid beneficiary if, among other requirements, the prescription drugs were medically necessary and ordered by a physician. As part of the process to become a Medicaid provider, health care practitioners were required to acknowledge that they understood and would abide by Medicaid’s rules, regulations, and program requirements.

COUNT ONE

**CONSPIRACY TO DEFRAUD THE UNITED STATES
AND TO VIOLATE THE ANTI-KICKBACK STATUTE**

[18 U.S.C. § 371]

THE GRAND JURY CHARGES THAT:

21. Paragraphs 1 through 20 of the Superseding Indictment are realleged and incorporated by reference as though fully set forth herein.

22. From on or about October 10, 2014, and continuing through in or around September 2016, in the Southern District of Ohio and elsewhere, the defendant NICOLE GEORGES did knowingly and willfully combine, conspire, confederate, and agree with Jimmy Henry, and others known and unknown to the Grand Jury, to commit certain offenses against the United States, that is:

- a. to defraud the United States by cheating the United States government or any of its departments or agencies out of money and property, and by impairing, impeding, obstructing, and defeating through deceitful and dishonest means, the lawful government functions of CMS in its administration and oversight of Medicare and Ohio Medicaid; and
- b. to offer and pay remuneration, directly and indirectly, overtly and covertly, in cash and in kind, that is, kickbacks and bribes, on behalf of Insys, to induce physicians and other health care professionals to purchase, order, and arrange for goods, services, and items, that is, to write prescriptions for Subsys, for which payment may be made in whole and in part by a Federal health care program, in violation of Title 42, United States Code, Section 1320a-7b(b)(2)(B).

Purpose of the Conspiracy

23. It was the purpose of the conspiracy for NICOLE GEORGES and her co-conspirators to unlawfully enrich themselves and others by, among other things, (a) soliciting, receiving, offering, and paying kickbacks and bribes in exchange for writing prescriptions for Subsys; (b) submitting and causing the submission of false and fraudulent claims to Medicare and ODM for the dispensing of Subsys that were ordered and prescribed through kickbacks and bribes, were medically unnecessary, and were ineligible for reimbursement; (c) concealing the submission of false and fraudulent claims to Medicare and Medicaid and the receipt and transfer of the proceeds of the fraud; and (d) diverting fraud proceeds for their personal use and benefit, for the use and benefit of others, and to further the fraud.

Manner and Means of the Conspiracy

The manner and means by which defendant NICOLE GEORGES and her co-conspirators sought to accomplish the purposes of the conspiracy included, among others:

24. It was part of the conspiracy that Insys, by and through its officers, managers, and employees, would and did design and implement a program known as the Insys Reimbursement Center to facilitate the approval of insurance forms, including those submitted for Midwest patients who were Medicare and Ohio Medicaid beneficiaries, to ensure approval of and payment for Subsys prescriptions by Medicare, Ohio Medicaid, and other insurers.

25. It was part of the conspiracy that Insys, by and through its officers, managers, and employees, would and did design and implement an illegal kickback and bribery scheme to induce Henry, and others, to prescribe Subsys instead of other medications, and for conditions other than for which Subsys was medically indicated, namely, breakthrough cancer pain.

26. It was part of the conspiracy that Insys would and did hire sales representatives, including GEORGES, to solicit medical professionals such as Henry to write Subsys prescriptions and to facilitate and help secure insurance approvals for those Subsys prescriptions.

27. It was part of the conspiracy that GEORGES was hired by Insys on or around June 2, 2014 as a Specialty Sales Professional.

28. It was part of the conspiracy that GEORGES attended Subsys Training held by Insys representatives from approximately June 17 through June 20, 2014. At this training, GEORGES learned the FDA-approved indication for Subsys. GEORGES was also required to demonstrate that she knew how to perform the following tasks: list all of the Subsys clinical benefits; go through the REMS enrollment procedure; assist the patient in a free product trial; opt-in the patient to IRC for prescription authorization assistance; and gain co-pay assistance for the patient.

29. It was part of the conspiracy that as part of this training, GEORGES had to prove to Insys representatives that she knew the indication for Subsys, its Black Box warning² and how to use the actual Subsys device.

30. It was part of the conspiracy that, in order to conceal and disguise that kickbacks and bribes were being paid to induce Henry and other medical professionals to prescribe Subsys, Insys would and did designate payments to Henry and other medical professionals as reimbursement for purportedly providing educational presentations regarding Subsys. Insys called this program the "Insys Speaker Program."

² A black box warning is the most severe warning the FDA can issue and appears on a prescription drug's label to call attention to serious or life-threatening risks.

31. It was part of the conspiracy that Insys officials publicly claimed that the purpose of the Insys Speaker Program was to educate other providers concerning the benefits of Subsys. In reality, the primary purpose of the Insys Speaker Program was to provide a financial reward to providers, like Henry, who were prescribing large amounts of Subsys and to incentivize those providers to continue to prescribe Subsys in the future.

32. It was part of the conspiracy that GEORGES would and did use the Insys Speaker Program to induce Henry and others to order and write new prescriptions for Subsys to Midwest patients.

33. It was part of the conspiracy that on or about October 10, 2014, Henry entered into a purported "Speaker Agreement" with Insys. Henry signed additional Speaker Agreement contracts on October 28, 2015 and August 6, 2016. GEORGES was involved in facilitating Henry's engagement with Insys through the Insys Speaker Program. Pursuant to the agreement, Henry would receive approximately \$2,200 from Insys per speaking engagement.

34. It was part of the conspiracy that GEORGES commonly worked out of Midwest and coordinated the alleged speaking events pursuant to Henry's Speaker Agreement contracts, including scheduling and often catering the purported Speaker Agreement events. GEORGES prepared sign-in sheets which allegedly bore the signatures of participants of the purported speaking events. GEORGES then submitted this documentation about the purported speaking events to Insys so that Henry would be paid pursuant to his Speaker Agreement contracts.

35. Many of the speaking events purportedly conducted by Henry, which were facilitated by GEORGES and for which he received payment from Insys, were sham events. On some occasions, Henry did not even attend the purported speaking event. On the occasions he

did attend, Henry discussed his own pain management practice and did not train prescribers or other practitioners on Subsys as outlined in his Insys Speaker Program contracts.

36. It was part of the conspiracy that GEORGES caused speaker fees to be paid to Henry only after he and those under his supervision at Midwest wrote more prescriptions for Subsys, including prescriptions for Medicare and Ohio Medicaid beneficiaries that were paid for by Federal health care benefit programs.

37. It was part of the conspiracy that during the time that Henry participated in the Insys Speaker Program, the number of prescriptions that Henry wrote for Subsys that were reimbursed through Medicare and Ohio Medicaid increased substantially. As Henry's compensation from Insys increased in 2014 and early 2015, so did his prescriptions of Subsys and the Medicare and Ohio Medicaid Program reimbursement therefrom. After Henry stopped participating in the Insys Speaker Program in or around September 2016, his prescribing of Subsys decreased substantially.

38. It was part of the conspiracy that Henry, and others under his supervision at Midwest, issued and caused to be issued prescriptions for Subsys that were not medically necessary, in that they were prescribed outside the usual course of professional practice and without a legitimate medical purpose to patients whose diagnoses and circumstances did not support issuing Subsys prescriptions and for conditions for which Subsys was not medically indicated.

39. It was part of the conspiracy that GEORGES and others completed prior authorization and TIRF REMS paperwork with Midwest patients. GEORGES submitted documentation to the Insys Reimbursement Center to facilitate payment for the Subsys

prescriptions from insurance companies, including Federal health care programs Medicare and Ohio Medicaid.

40. Beginning in or about November 2014 and continuing through at least September 2016, Federal health care benefit programs including Medicare and Ohio Medicaid authorized payments for hundreds of Subsys prescriptions written by Henry, and others under the supervision of Henry, which were medically unnecessary and induced by Henry's participation in the sham Insys Speaker Program.

Overt Acts

41. In furtherance of the conspiracy, and to accomplish its purposes and objects, the defendant, NICOLE GEORGES, together with others known and unknown to the United States, committed and caused others to commit at least one of the following overt acts, among others, in the Southern District of Ohio and elsewhere:

a. On or about January 21, 2015, GEORGES submitted falsified paperwork to Insys indicating that Henry reportedly completed a speaking event at Kaplansky Foot and Ankle in Columbus, Ohio when, in truth and in fact, Henry did not participate in the speaking event. A representative of Kaplansky Foot and Ankle indicated that no such training occurred on that date, and that the practice would have no occasion to prescribe Subsys in a podiatric setting. Based on the fraudulent paperwork GEORGES submitted, Insys paid Henry a kickback totaling approximately \$2,200.

b. On or after May 1, 2015, GEORGES submitted falsified paperwork to Insys indicating that Henry completed a speaking event at Darby Creek Medical

Practice when, in truth and in fact, Henry did not participate in the speaking event. A representative of Darby Creek Medical Practice had no recollection of such a speaking event, and that the Ohio Health Group which operates the practice would never authorize an event relating to Subsys. Further, the representative denied that the signature on the sign-in sheet GEORGES submitted was her signature. Based on the fraudulent paperwork GEORGES submitted, Insys paid Henry a kickback totaling approximately \$2,200.

c. On or after September 11, 2015, GEORGES submitted falsified paperwork to Insys indicating that Henry completed a speaking event at Central Ohio Primary Care – Arlington Mill Run (“COPC”) in Columbus, Ohio when, in truth and in fact, Henry did not participate in the speaking event. A representative of COPC denied that practitioners at COPC had ever been a party to a training by Henry, or to any other presentation about Subsys such as the one Henry was reported to have conducted. Based on the fraudulent paperwork GEORGES submitted, Insys paid Henry a kickback totaling approximately \$2,200.

d. The last speaking event for which GEORGES submitted Speaker Program paperwork to Insys on Henry’s behalf, in order to facilitate kickback payments to Henry, was purportedly held on approximately August 6, 2016.

e. Based on falsified documentation submitted by GEORGES and co-conspirators known and unknown to the Grand Jury, Insys paid Henry approximately \$60,900 in bribes and kickbacks resulting from Henry’s participation in the Insys Speaker Program. These kickback payments purportedly

related to approximately 30 speaking events GEORGES, and others aiding and abetting GEORGES, allegedly coordinated from November 2014 through August 2016.

f. Henry, and those under his supervision at Midwest, continued to prescribe Subsys to Midwest patients through at least February 2018 in a manner that was medically unnecessary, for conditions that were not medically indicated, and induced by the kickbacks from Insys which were facilitated by GEORGES.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO

VIOLATION OF THE ANTI-KICKBACK STATUTE

[42 U.S.C. § 1320a-7b(b)(1)(B)]

THE GRAND JURY FURTHER CHARGES THAT:

42. Paragraphs 1 through 20 and 23 through 41 of the Superseding Indictment are realleged and incorporated by reference as though fully set forth herein.

43. On or about the date listed below, in the Southern District of Ohio and elsewhere, defendant NICOLE GEORGES, aiding and abetting Jimmy Henry and aided and abetted and others known to the Grand Jury, did knowingly and willfully solicit and receive the remuneration listed below, directly and indirectly, overtly and covertly, in cash and in kind, in return for purchasing, leasing, ordering, and arranging for and recommending purchasing, leasing, and ordering any good, facility, service, and item, that is, a significant increase in the number of Subsys prescriptions, for which payment may be made in whole and in part under Federal health care programs, those are, Medicare and Ohio Medicaid:

Approximate Date Payment Received	Payment Amount	Date and Location of Purported Speaking Program
9/24/2015	\$2,200	9/11/2015, Arlington Mill Run – Central Ohio Primary Care, Columbus, Ohio

In violation of 42 U.S.C. § 1320a-7b(b)(1)(B) and 18 U.S.C. § 2.

FORFEITURE ALLEGATIONS

The GRAND JURY further alleges:

44. Paragraphs 1 through 43 of the Superseding Indictment are realleged and incorporated by reference as though fully set forth herein.

45. The allegations contained in Counts 1 and 2 of this Superseding Indictment are incorporated here for the purpose of alleging forfeiture pursuant to the provisions of Title 18, United States Code, Section 982.

46. Upon conviction of the offenses in violation of a federal health care offense, including a violation of Title 18, United States Code, Section 371 as set forth in Count 1 or a violation of Title 42, United States Code, Section 1320a-7b(b)(1)(B) as set forth in Count 2, defendant NICOLE GEORGES shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offenses.

47. If any of the property described above as being subject to forfeiture, as a result of any act or omission of the defendant:

- i. cannot be located upon the exercise of due diligence;
- ii. has been transferred or sold to, or deposited with, a third party;
- iii. has been placed beyond the jurisdiction of the Court;
- iv. has been substantially diminished in value; or

v. has been commingled with other property that cannot be subdivided
without difficulty;

the defendant shall forfeit to the United States any other property of the defendant, up to the value of the property described above, pursuant to Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

All pursuant to Title 18, United States Code, Section 982(a)(7), and Title 28, United States Code, Section 2461(c).

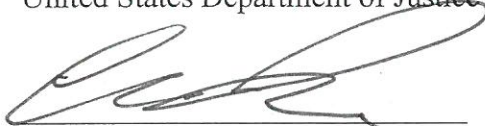
A TRUE BILL:

/s/ signed
FOREPERSON

VIPAL J. PATEL
Acting United States Attorney

DANIEL KAHN
Acting Chief
Fraud Section, Criminal Division
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ALLAN J. MEDINA
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